Certificate

Full Quality Assurance System Approval

Annex II excluding (4) of the Directive on Medical Devices

ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that an examination of the undermentioned quality assurance system has been carried out following the requirements of annex II excluding (4) of the Directive 93/42/EEC.

This certificate is issued on behalf of:

VSY Biotechnology BV

Strawinskylaan 1143, 1077 XX Amsterdam, The Netherlands

ECM certifies that the full quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex II excluding (4) of the Directive 93/42/EEC on medical devices.

The approved quality assurance system is subject to periodic surveillance as defined by annex II excluding (4), section 5.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex II of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Audit Report Number	Registered under	Valid until
565-18-94	**Z/18/04341E**	**November 18th, 2023**

Valid as of: November 19th, 2018

Certification Body

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de

ZLG-BS-240.10.12

Annex I of Certificate Z/18/04341E

ecm
Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type
Ophthalmic and optical products:	Lenses, Intraocular, Posterior Chamber - Acriva - Ocuva
Ophthalmic and optical products:	Inserters, Intraocular Lens: - AcriJET
Ophthalmic and optical products	Ophthalmic viscosurgical devices - Protectalon 1.0%, 1.2%, 1.4%, 1.6%, 1,8%, 2.0%
non active implantable products	Intra-articular Viscosupplement Medical Devices Reviscon 1.0 % Reviscon Plus 1.6% Romova Plus 1.6 %

Special terms of validity:

None.

' UMDS Code is optional